REMARKS

Claims 19, 23-25, and 28-29 have been examined on their merits, and stand rejected as indefinite and/or obvious in view of the cited references. Claims 21, 22, 24-27 and 30-39 have been withdrawn by the Examiner as directed to non-elected subject matter. Applicants expressly reserve the right to file one or more continuation or divisional application(s) directed to the non-elected subject matter that is not rejoined with this application. Claims 1-18 have been previously cancelled.

Applicants have amended claim 19. In view of the amendments and remarks below, Applicants respectfully request that the rejections be reconsidered and withdrawn.

35 U.S.C. § 112

Claims 19, 23-25, 28 and 29 stand rejected under 35 U.S.C. § 112, second paragraph, as being indefinite with respect to the recitation of "that suffers or will suffer from." In the Office Action, the Examiner states that the preamble in claim 19 recites "a mammal suffering from trauma," and this does not support the limitation "said mammal that suffers from or will suffer from said trauma." Applicants have amended the preamble in claim 19 to be consistent with the limitation "will suffer from said trauma". Accordingly, withdrawal of this rejection is respectfully requested.

35 U.S.C. § 103

Claims 19, 23-25, 28 and 29 stand rejected under 35 U.S.C. § 103(a) as obvious over Alexander[1].

Claim 19 is directed to a method of reducing the risk of developing multiple organ dysfunction (e.g. organ failure) in a mammal. In contrast, Alexander is directed to stimulating or re-stimulating the immune system where the immune system was compromised after trauma.

[1] United States Patent No. 5,231,085 to Alexander *et al.* (Alexander).

Thus, the recited multiple organ dysfunction is different from the condition being treated in Alexander. Since Alexander does not teach or suggest inducing the risk of multiple organ dysfunction, claim 18 and the claims depending therefrom, are patentable over Alexander.

Furthermore, Alexander states that its immunostimulatory compositions comprise a compound associated with the synthesis of polyamines, a nucleobase source, an omega-3 polyunsaturated fatty acid, and an omega-6 polyunsaturated fatty acid.[2] It states that the nucleobase could be one of at least 23 different nucleobases, one of them being guanosine. In fact, Compound A, which the Examiner specifically cites, does not contain guanosine. Instead, it contains a mixture of the following nucleobases: uracil, cytosine, guanine, adenine and thymine.[3] And while Compound A contains a "carbohydrate source," namely maltodextrins, Alexander only mentions that a carbohydrate source may be used without providing a specific motivation to combine the recited digestible water soluble with guanosine.

A combination of known elements will not yield predictable results if the references disclose a broad selection of compounds or combinations, or if the references teach away from the claimed invention. See *Takeda Chemical*, 492 F.3d at 1359; also see *Ortho-McNeil Pharmaceutical, Inc. v. Mylan*, 520 F.3d 1358, 1364 (Fed. Cir. 2008); and also see *Ex parte Ikeda*, App. No. 08/352,079, Appeal 2008-0492, Slip Op. at 7 (BPAI Mar. 26, 2008). Here, there is no teaching or suggestion to combine guanosine and a digestible water soluble carbohydrate because there is no reason to pick-over the over 23 different nucleobases to just use guanosine, or to add a carbohydrate that is digestible and water soluble. Furthermore, there is no reason provided why one would have expected such a combination to be useful in the recited method – to reduce the risk of developing multiple organ dysfunction.

In addition to the above, claim 25 is separately patentable over Alexander. Claim 25, which depends from claim 23, further recites that "the liquid composition is administered within 24 hours prior to the occurrence of the surgery." In contrast, Alexander teaches

[2] Alexander at column 2, lines 19-26.

[3] Alexander at column 6, lines 23-27.

administering its compound at 11:00 am on the first postoperative day, which is greater than 24 hours prior to the occurrence of surgery because the first postoperative day is approximately 24 hours after surgery. Thus, for this additional reason, claim 25 is patentable over Alexander.

Response to Office Action

On page 9 of the Office Action, the Examiner contends that the limitation "reducing the risk of developing organ dysfunction" is an intended use that does not require a manipulative difference and therefore is not a claim limitation. Applicants respectfully disagree because claim 19 is a method claim, not a composition claim. As stated in MPEP § 2112.02, "[t]he discovery of a new use for an old structure based on unknown properties of the structure might be patentable to the discoverer as a process of using. *In re Hack*, 245 F.2d 246, 248, 114 USPQ 161, 163 (CCPA 1957)." This rule is the basis for numerous pharmaceutical patents directed to methods of treating a disease, illness or condition by administering known compounds (see, for example, U.S. Pat. No. 6,337,329 to Cochran *et al.* claiming "a method of treating an ophthalmic infection" wherein the compound administered was known).

Moreover, the claims are directed to administering the recited liquid composition to those who are or about to suffer from a trauma. This is a manipulative difference because it requires identifying a person who is or about to suffer from trauma.

The Examiner further contends that "Alexander teach in one example (column 7 line 21-23) that administration was within 24 hours of injury."[4] This portion of Alexander states that "each [patient] was maintained on parenteral nutrion begun within 24 hours of injury and having the general formula: 1.5-2.0 g/kg/day of amino acids, 1.0 g/kg/day of fat, and the remaining calories as glucose at 30-35 kcal/kg/day."[5] This only suggests that patients were fed after surgery, not that the patients were administered Alexander's Composition A, which is capable of enhancing the immune system. While this passage teaches that the nutrition that the

[4] Office Action at page 10.

[5] Alexander at col. 7, lines 21-26.

patients received contained glucose, it makes no mention that GTP was part of the nutrition administered. Additionally, this does not suggest that Alexander's "Composition A" was administered during this time. Since Alexander only suggests administering a nutritional composition, not compound A, within the first 24 hours after surgery, and since this nutritional composition did not contain guanine or any other nucleobase, nucleoside or nucleotide, even if Alexander suggests administering GTP and glucose in Composition A, it does not do so within 24 hours after surgery.

Furthermore, the claims recite "... enterally administering to said mammal an aqueous liquid composition ..." (claim 19). Alexander teaches administering the nutritional composition parenterally, not enterally, within 24 hours after surgery.[6]

For these reasons, Applicants respectfully request that this rejection be reconsidered and withdrawn.

REQUEST FOR REJOINDER

Applicants respectfully request that claims 20, and 24-27, which are drawn to non-elected species, be examined and allowed because claim 19 is a generic claim that encompasses that species recited in claims 20 and 24-27, and because claim 19 is in condition for allowance.[7] The Applicants further request that the non-elected claims 30-36 be rejoined.[8]

Claims 37-39

Additionally, in the Amendment of April 1, 2010, Applicants added claims 37-39. These claims depend from claim 19 and add further limitations, namely, folic acid (claim 37), a peptide (claim 38), and a flavonoid (claim 39). According to the Office Action dated July 30, 2010, these claims are directed to non-elected species because they are not a guanosine or glucose. Applicants respectfully disagree because claim 37-39 are dependent claims that add

[6] Alexander at col. 7, lines 21-26.

[7] See MPEP § 809.02(a).

[8] See MPEP § 821.04.

additional limitations. For example, assuming that the claims are limited to only the elected species (guanosine and glucose), claim 37 is directed to a composition comprising guanosine, glucose and folic acid. Claim 19 is not limited so as to exclude other compound from the liquid composition. Thus, even though the Applicants elected with traverse the guanosine and glucose species, this election does not transform claim 19 into a closed claim wherein additional compounds cannot be added. Instead, claim 19, which uses the transition phrase "comprising," is open and can include additional compounds such as folic acid, proteins, and flavonoids.

For this reason, Applicants respectfully request that claims 37-39 be considered on their merits.

CONCLUSION

In view of these amendments and remarks, Applicants respectfully request that the objections and rejections be reconsidered and withdrawn, that claims 19, 21-23, 28-29 and 37-39 be allowed, and that claims 20, 24-27 and 30-36 be rejoined.

Respectfully submitted,

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